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Brief Communication

# Positional therapy for obstructive sleep apnea: An objective measurement of patients' usage and efficacy at home

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#### ABSTRACT

*Background:* Positional therapy that prevents patients from sleeping supine has been used for many years to manage positional obstructive sleep apnea (OSA). However, patients' usage at home and the long term efficacy of this therapy have never been objectively assessed.

*Methods:* Sixteen patients with positional OSA who refused or could not tolerate continuous positive airway pressure (CPAP) were enrolled after a test night study (T0) to test the efficacy of the positional therapy device. The patients who had a successful test night were instructed to use the device every night for three months. Nightly usage was monitored by an actigraphic recorder placed inside the positional device. A follow-up night study (T3) was performed after three months of positional therapy.

*Results*: Patients used the device on average 73.7 ± 29.3% (mean ± SD) of the nights for 8.0 ± 2.0 h/night. 10/16 patients used the device more than 80% of the nights. Compared to the baseline (diagnostic) night, mean apnea–hypopnea index (AHI) decreased from  $26.7 \pm 17.5$  to  $6.0 \pm 3.4$  with the positional device (p < 0.0001) during T0 night. Oxygen desaturation (3%) index also fell from  $18.4 \pm 11.1$  to  $7.1 \pm 5.7$  (p = 0.001). Time spent supine fell from  $42.8 \pm 26.2\%$  to  $5.8 \pm 7.2\%$  (p < 0.0001). At three months (T3), the benefits persisted with no difference in AHI (p = 0.58) or in time spent supine (p = 0.98) compared to T0 night. The Epworth sleepiness scale showed a significant decrease from  $9.4 \pm 4.5$  to  $6.6 \pm 4.7$  (p = 0.02) after three months.

*Conclusions:* Selected patients with positional OSA can be effectively treated by a positional therapy with an objective compliance of 73.7% of the nights and a persistent efficacy after three months.

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#### 1. Introduction

The influence of body position on obstructive sleep apnea (OSA) is well recognized, with an increase in sleep disordered breathing severity in the supine posture [1,2], most likely due to an increase in upper airway collapsibility [3] and to a posterior displacement of the tongue [4]. Upper airway collapsibility can also increase with decreased lung volume, which occurs in supine position due to a rostral displacement of the diaphragm, especially in the patients with large abdominal mass [5–7]. Moreover, microgravity during space flight reduces sleep apnea and virtually suppresses snoring [8], which confirms the effect of gravity on sleep disordered breathing.

\* Corresponding author. Address: Pulmonary Department, Center for Investigation and Research in Sleep (CIRS), Lausanne University Hospital (CHUV), 1011 Lausanne, Switzerland. Tel.: +41 21 314 67 54; fax: +41 21 314 67 52. The prevalence of positional sleep apnea varies from 50% to 60% of all OSA patients according to the various definitions of the condition. Some authors define positional sleep apnea as a 50% reduction in apnea–hypopnea index (AHI) during non-supine sleep, while others use more stringent criteria, requiring a 50% reduction and AHI <5/h in a non-supine posture [9].

Numerous positional therapy strategies have been developed to prevent OSA patients from sleeping in a supine position. One of them, the so-called "tennis ball technique" (a tennis ball fastened to the back with a belt or sewn into the patient's pajamas) has been shown to significantly decrease supine sleep time and to decrease AHI from  $46.5 \pm 19.9$  to  $17.5 \pm 19.4$  in 12 positional OSA patients [10]. Permut et al. recently reported that positional therapy was equivalent to CPAP in reducing AHI to less than 5/h in mild to moderate positional OSA [11]. Another study showed that 13 out of 18 positional OSA patients could be successfully treated with this technique [12]. Unfortunately, compliance (assessed with questionnaires) is poor, with 38% of patients still using the device after

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**Fig. 1.** Positional device used in this study (courtesy of Amrein Orthopédie, Lausanne Switzerland). (1) Firm plastic piece making supine posture uncomfortable. (2) Shoulder straps preventing the device from moving during the night.

six months and less than 6% at 2.5 years, with high variability between individuals and age groups [10,13]. Moreover, the long-term efficacy of this device has not been proven at home. Given these poor results, this type of therapy is not considered a first line treatment by most clinicians [14].

In our centre, we use a positional device derived from the tennis ball technique, with a firm plastic piece applied on the back at the scapula level (Fig. 1) making a supine position uncomfortable. Shoulder straps prevent the plastic piece from moving to the side, which is the main problem with the traditional tennis ball technique. Given the lack of objective data on compliance and longterm efficacy at home with this type of device, positional therapy is usually used only as a secondary therapy (i.e., in patients who did not tolerate CPAP or a dental appliance). The aims of this study were to: (1) measure objective nightly usage of this positional device at home and (2) assess its efficacy after three months of treatment at home.

#### 2. Materials and methods

Patients diagnosed with mild to severe positional OSA (defined as a >50% reduction in AHI and an AHI <10/h during sleep in nonsupine posture) during a home diagnostic night study (baseline, night 1) were identified in our sleep centre population. Night recordings were performed at home with limited channels (type III) recorders (Embletta, Embla System, Bloomfield, CO), which record nasal pressure, oxygen saturation, thoracic and abdominal movements, heart rate, and body posture. There was, however, no direct recording of the snoring. Sleep recordings' data were visually scored by an experienced clinician blinded to the study objective (GL). At least 1 h recording' in the supine position was required during the diagnostic night to assess the presence of positional OSA. Apnea was defined as complete cessation of airflow for at least 10 s. Hypopnea was defined as a >50% reduction in airflow associated with oxygen desaturation of 3%. The apnea-hypopnea index (AHI) was calculated as the total number of apnea plus hypopnea per hour of recording.

Twenty consecutive patients with positional OSA who did not tolerate (or refused) CPAP or oral appliances were offered the opportunity to participate. They all had a test night recording at home with the positional device (T0) as recommended by AASM guidelines [15]. Three patients were excluded because they had an AHI >10/h and one because he spent more than 10% of the night in supine position during T0 night. Sixteen patients who could tolerate the device, spent less than 10% of the night in supine position, and



**Fig. 2.** Example of actigraphy recording showing nightly usage in one subject over 45 days. The actigraphic recorder was placed inside the positional device. When the patients use the device during the night, movements were recorded (vertical lines). When it was not used (during the day) there was no movement (flat sections).

had an AHI <10/h during this "test" night were enrolled in the study. They were equipped with the positional device (Fig. 1) bought from Amrein Orthopédie (Lausanne, Switzerland). An actigraphic device (movement sensor recorder system, Actiwatch, CamNtech Ltd., Cambridge, UK) was inserted inside the positional device in order to assess compliance, i.e., detect when they used it (movements; vertical lines on Fig. 2) and when they did not (no movements; flat lines on Fig. 2). The start time was defined as the first vertical line at the beginning of the period where there were obvious movements and the stop time as the end of the last vertical line prior to a prolonged period where the signal was flat. Patients were instructed to use the positional device every night and for the whole night. They were informed of the presence of the movement sensor for ethical reasons. After a three month period, data from the actigraphs were downloaded and a follow-up night study (T3; night 3) with the positional device was performed again at home. Data are reported as mean ± standard deviation (SD). Statistical analysis (repeated measures ANOVA, Spearman's rank correlation, and paired *t*-tests) was performed using SigmaStat software version 3.0 (Systat Software, San Jose, CA). This study was approved by the University of Lausanne Institutional Ethic Committee (no IRB number) and each subject gave informed consent.

#### 3. Results

Demographic and sleepiness data of the 16 patients are reported in Table 1. Compared with the four patients excluded after baseline recording, the age, body mass index (BMI), mean AHI, and Epworth of the patients included were not significantly different (age p = 0.85, BMI p = 0.58, AHI p = 0.74, Epworth p = 0.98). During

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Baseline

Table 1Demographic and sleepiness data of the subjects.

Patients ( $n = 16$ )	Mean	SD
Age (year)	58.4	15.1
Male gender %	81.2	
BMI (kg/m <sup>2</sup> )	25.4	4.1
AHI (Baseline)	26.7	17.5
Epworth score (baseline)	9.4	4.5

BMI = body mass index, AHI = apnea-hypopnea index.

the 90 days period of the study, two of the 16 subjects stopped using the positional device: one because of back pain and another because of a broken clavicle (car accident). All the 14 remaining patients continued using the device even after the 90 day study period. At three months an additional night study was performed with the positional device in 12 patients; two declined this third recording but continued using the device. According to the actigraphy recordings (Fig. 2), the patients used the device  $73.7 \pm 29.3\%$  of the nights (range 9–100%) for an average of  $8.0 \pm 2.0$  h/night (range 3.8–10.6 h). Ten patients used the device more that 80% of the nights, and 13 more than 60% of the nights.

The main results of the three night recordings (baseline, T0 and T3) are displayed in Table 2. During the first night with the positional device (T0) compared to the baseline (diagnostic) night, mean AHI decreased from  $26.7 \pm 17.5$  to  $6.0 \pm 3.4$  (p < 0.0001), oxygen desaturation (3%) index fell from  $18.4 \pm 11.1$  to  $7.1 \pm 5.7/h$ (p = 0.001) and the proportion of the recording time spent supine fell from  $42.8 \pm 26.2\%$  to  $5.8 \pm 7.2\%$  (p < 0.0001) (Fig. 3). When the three most severe patients at baseline (AHI >40/h) were excluded from the statistics, the mean AHI for baseline, TO, and T3 was  $19.8 \pm 5.5$ ,  $6.2 \pm 2.8$ , and  $7.1 \pm 5.2$ , respectively, and the difference in AHI with the positional device remained highly significant (p < 0.001). Compared to the first night with the positional device (T0), the recording performed after three months (T3) showed a persistent effect with no significant difference in AHI (p = 0.58), oxygen desaturation index (p = 0.15), or time spent in the supine position (p = 0.98). At baseline (T0) a positive correlation between BMI and the decrease in AHI was found between the supine and the non-supine posture (R = 0.536, p = 0.038). The patients' BMIs did not change significantly  $(25.4 \pm 4.1 \text{ vs. } 25.6 \pm 3.5 \text{ kg/m}^2, p = 0.64)$ during the three month observation period. Sleepiness, as estimated by the Epworth sleepiness scale, showed a significant decrease after three months of positional device usage, decreasing from  $9.4 \pm 4.5$  (T0) to  $6.6 \pm 4.7$  (T3) (p = 0.02).

#### 4. Discussion

Table 2

The main finding of this study is that selected patients with mild to severe positional OSA can be effectively treated by a

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Main result	s of the	night	recordings

Effect of the Positional Device on Apnea Hypopnea Index
90
80
70
60
50
40
30
20

**Fig. 3.** Apnea–hypopnea index during "baseline" = diagnostic night (N = 16), T0 = first night test with the positional device (N = 16), and T3 = three months follow up night with the positional device (N = 12).

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positional device, with an effect that persists over three months. The compliance, measured using an actigraphic device, was estimated at 73.7% of the nights. To our knowledge, this is the first study measuring objective compliance of a positional therapy at home over time.

Two previous studies assessed compliance with positional devices using self-report questionnaires. Oksenberg et al. showed a low compliance rate at six months (38%) and Bignold found only 10% of the patients using the tennis ball technique 30 months after prescription [10,13]. In these studies the main cause of discontinuation was discomfort. One possible explanation for the much higher compliance rate found in the present study is that the positional device offered a more comfortable use due to the smaller volume of the rigid parts (two plastic bumps applied at the scapula level) instead of a tennis ball sewn on the back of the pajamas. The shoulder straps also prevented the device from moving to the side. which probably make it more efficient than a tennis ball, which can move to the side during the night. The stringent selection of the patients is another important factor that may have influenced the high compliance rate in our study: only patients with clear positional OSA (>50% reduction in AHI and an AHI <10/h in non-supine posture) who could tolerate the positional device on the test night were included for the three months follow up assessment. As recommended by AASM clinical guidelines [15], it seems that patient selection with a test night needs to be performed before positional therapy is prescribed in order to reach a reasonable compliance rate. Another potential reason is that the two other studies were much longer in duration. A longer follow-up would thus be needed for direct comparison.

Due to the lack of data on the efficacy and the poor compliance, positional therapy devices are usually prescribed only in patients who do not tolerate conventional therapies such as CPAP or mandibular advancement appliance (MAA) [14,15]. In the present

	Baseline $(N = 16)$	T0 ( <i>N</i> = 16)	T3 ( <i>N</i> = 12)	Baseline vs. TO	T0 vs. T3 (3 months use)			
Recording time (min)	476 ± 64	$485 \pm 80$	463 ± 77					
AHI (events/h)	26.7 ± 17.5	$6.0 \pm 3.4$	$10.3 \pm 8.2$	P = <b>0.0002</b>	P = 0.58			
Oxygen desat./h	18.4 ± 11.1	7.1 ± 5.7	$10.6 \pm 6.1$	P = <b>0.001</b>	P = 0.15			
Mean oxygen sat (%)	93.7 ± 1.3	94.7 ± 1.8	$94.3 \pm 0.9$	P = 0.071	P = 0.9			
Min oxygen sat (%)	84.7 ± 3.8	87.3 ± 4.3	87.2 ± 3.4	P = <b>0.048</b>	P = 0.94			
Time <90% SaO <sub>2</sub> (%)	2.88 ± 3.00	$0.90 \pm 2.08$	$0.73 \pm 0.73$	P = 0.137	P = 0.544			
Time supine (%)	42.8 ± 26.2	$5.8 \pm 7.2$	$4.6 \pm 5.0$	P < <b>0.0001</b>	P = 0.98			
AHI supine	54.0 ± 21.2	32.9 ± 19.2	$39.4 \pm 24.6$					
AHI non supine	$5.6 \pm 5.0$	$5.0 \pm 3.6$	$8.7 \pm 7.4$					

Baseline = diagnostic recording, T0 = test night with the positional device, T3 = three months follow up night with the positional device, AHI = apnea–hypopnea index, oxygen desat = number of 3% oxygen saturation drops per hour, min oxygen sat (%) = minimal oxygen saturation observed during the night recording, time <90% SaO<sub>2</sub> = percentage of the recording spent with an oxygen saturation level below 90%.

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study the compliance rate of 8 h/night, 78% of the nights favorably compares with MAA and CPAP usage. Barnes et al. compared adherence to CPAP and MAA in mild to moderate OSA over three months; lower compliance rates were observed following CPAP  $(3.6 \pm 0.3 \text{ h/night}, 4.2 \text{ night/week})$  and MAA  $(5.5 \pm 0.3 \text{ h/night}, 5.3 \pm 0.3 \text{ night/week})$  [16]. In other studies, MAA reported wearing time was 7.0 ± 0.2 h, 5.7 night/week [17], and CPAP usage was even lower at 3.9 h/night with 48.9% of the patients using it >4 h/night [18]. Moreover the ability of the positional device used in our study to reduce daytime sleepiness (Epworth score) also favorably compares with CPAP and MAA therapies [19–21].

We found a significant decrease in AHI between baseline and T0 nights, which we attributed to the effect of the positional device since it reduced the time spent supine. At baseline there was also a significant correlation between BMI and the decrease in AHI between supine and non-supine posture. One possible explanation for this finding is that the upper airway is more collapsible in the supine position due to a rostral displacement of the diaphragm in patients with a large abdominal mass, since upper airway collapsibility increases with decreased lung volume [7]. After three months of positional device usage (T3), the time spent supine and the AHI did not change significantly even though there was a trend toward an increase in AHI (Table 2). We could not find any clear explanation for this mild increase in AHI since BMI and time spent supine did not significantly change.

There are also a few technical considerations regarding this study. First, the sleep recordings were performed at home with limited channel recorders (without EEG) and did not allow the assessment of sleep quality. An impairment of sleep quality due to the positional device cannot be formally excluded. However, the significant decrease in sleepiness (Epworth score) and the good tolerance and compliance with the device suggest that sleep quality was not significantly impaired. Moreover, Permut et al. found no effect of their positional device on sleep efficiency, sleep duration, sleep architecture, and arousal index [11]. Second, our study lacks a control group without treatment during the same three month period. Obviously, such a control patient group without any treatment could be difficult to justify from an ethical point of view. Also, OSA does not usually improve without treatment unless there is a significant weight loss, which was not found in our population. Third, while nightly use was monitored with the actigraph, the effectiveness of the device at positioning the patient in the non-supine position was not monitored nightly, but only during TO and T3 sleep studies.

In conclusion, our findings suggest that, in selected patients with clear positional OSA and a positive test night, a comfortable positional device could be considered as a therapeutic option. In patients insufficiently treated with CPAP or MAA, a combined therapy with a positional device could also be considered. However, larger studies assessing the effect of this type of treatment on objective sleepiness and cardiovascular comorbidities are needed before positional treatment can be considered as a longterm valid and safe first line treatment for patients with various severities of OSA.

#### **Disclosure statement**

Dr. Tafti has received research support from, is on the advisory board of, and has participated in speaking engagements for UCB-Pharma. Dr. Lavigne has consulted or participated in speaking engagements for Pfizer Canada, Respironics-Philips USA, and UCB-Pharma. Dr. Rossetti received research support from UCB-Pharma, Janssen-Cilag, and Pfizer. The other authors have indicated no financial conflicts of interest.

#### **Conflict of interest**

The ICMJE Uniform Disclosure Form for Potential Conflicts of Interest associated with this article can be viewed by clicking on the following link; doi:10.1016/j.sleep.2011.11.004.

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All authors contributed to the design of the study. Data were collected by RH, CP, VR, AR, GP, and JHR. The manuscript was written by RH and GL and was reviewed by each author.

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